Paper No. 41

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

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Ex parte GRAHAM A.W. ROOK
and JENNIFER J. EDGE

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Appeal No. 1998-0968
Application No. 08/031,075

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ON BRIEF

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Before WILLIAM F. SMITH, SCHEINER and GRIMES, Administrative Patent Judges.

SCHEINER, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 22, 24, 32, 34, 35, 37, 45, 47, 48, 50, 60, 61, 63 and 73, all the claims under consideration in the application.[1]

[1] Claims 74 through 176 are also pending, but have been withdrawn from consideration as the result of a restriction requirement.

Claim 22 is representative of the claimed subject matter and read as follows:

22. A hybridoma which is capable of producing a monoclonal antibody which:
(i) has been raised against the cell walls of Group A Streptococci; and
(ii) is specific to mammalian cells or membranes, or mammalian immunoglobulins of the IgG class, containing terminal N-acetylglucosamine residues; wherein, in an enzyme-linked immunoabsorbent assay, said monoclonal antibody is:
(i) negative to fetuin; and
(ii) positive to:
(a) bovine serum albumin conjugated to N-acetylglucosamine residues;
(b) fetuin which has been treated with sialidase and galactosidase; and
(c) immunoglobulins which have been denatured.

Claims 22, 24, 32, 34, 35, 37, 45, 47, 48, 50, 60, 61, 63 and 73 stand rejected under 35 U.S.C. § 102(b) or, in the alternative, under 35 U.S.C. § 103.[2] As evidence of anticipation or obviousness, the examiner relies on Nahm[3] and Katz.[4]

DISCUSSION

Anticipation requires the disclosure, in a single prior art reference, of each element of the claim under consideration. W.L. Gore & Assoc. v. Garlock, Inc., 721 F.2d 1540, 1554, 220 USPQ 303, 313 (Fed. Cir. 1983), cert. denied, 469 U.S. 851 (1984). However, it has been held that additional evidence may be relied on in support of an anticipation

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[2] This rejection was set forth for the first time in the Examiner's Answer (paper no. 30). In the final office action (paper no. 25), the claims were rejected under 35 U.S.C. § 102(b) alone.

[3] Nahm et al. (Nahm), "Improved Diagnostic Accuracy Using Monoclonal Antibody to Group A Streptococcal Carbohydrate," Journal of Clinical Microbiology, Vol. 12, No. 4, pp. 506-508, October 1980.

[4] Katz et al. (Katz), WO 84/04169, October 25, 1984.

rejection. See In re Samour, 571 F.2d 559, 562, 197 USPQ 1, 3-4 (CCPA 1979). That is, "extrinsic evidence may be considered when it is used to explain, but not expand, the meaning of a[n] [anticipatory] reference." In re Baxter Travenol Labs, 952 F.2d 388, 390, 21 USPQ2d 1281, 1284 (Fed. Cir. 1991). Finally, it is well established that

> [A] prior art reference [that] does not expressly set forth a particular element of the claim . . . still may anticipate if that element is "inherent" in its disclosure. To establish inherency, the extrinsic evidence "must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill." Continental Can Co. v. Monsanto Co., 948 F.2d 1264, 1268, 20 U.S.P.Q.2d 1746, 1749 (Fed. Cir. 1991). "Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient." Id. at 1269, 20 U.S.P.Q.2d at 1749 (quoting in re Oelrich, 666 F.2d 578, 581, 212 U.S.P.Q. 323, 326 (C.C.P.A. 1981)).

In re Robertson, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999).

Nahm describes a hybridoma cell line secreting monoclonal antibody HGAC-1. The antibody was raised against a group A streptococcal vaccine and recognizes the terminal N-acetylglucosamine residue on the group A carbohydrate. In addition, "HGAC-1 binds to N-acetylglucosamine conjugated to bovine serum albumin, substantiating its specificity for the N-acetylglucosamine hapten." Page 507, right-hand column. There is no dispute that Nahm does not expressly describe an antibody which additionally binds mammalian cells or membranes, mammalian IgG, denatured immunoglobulins, and sialidase- and galactosidase-treated fetuin (but not untreated fetuin). Rather, the issue for our

consideration is whether Nahm's antibody necessarily (inherently) possesses these additional, undisclosed properties.[5]

The examiner relies on Katz as extrinsic evidence that Nahm's antibody, which recognizes the N-acetylglucosamine hapten, inherently binds mammalian IgG. As Katz explains, "[o]ne of the major antigenic determinants of Streptococcus Group A (Strep-A) is N-acetyl-D-glucosamine," and antibodies that bind the N-acetyl-D-glucosamine determinant will "self-bind," unless "monoclonal Anti-Streptococcal Group A antibody is cleaved to remove the Fc portion which includes an N-acetyl-D-glucosamine moiety." Katz, Page 1. Similarly, the examiner relies on the present specification as evidence that Nahm's antibody, specific for the N-acetylglucosamine hapten, inherently binds enzyme treated fetuin, but not native fetuin, inasmuch as "[f]etuin . . . contains N-acetylglucosamine normally hidden in its structure," but "[t]reatment with sialidase and galactosidase cleaves the molecule to expose the N-acetylglucosamine." Specification, page 3. In our view, the extrinsic evidence relied on supports the examiner's position, as far as it goes.

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[5] A recurring theme in appellants' arguments is that "there is nothing present in [Nahm] which suggests that [Nahm's] monoclonal antibody has the ability to bind mammalian cells or membranes," and "it was initially unexpected and surprising that monoclonal antibodies raised against the polysaccharide portion of the bacterial cell walls of Group A Streptococci . . . would bind to mammalian cells and membranes." Brief, pages 18 and 19. All such arguments are irrelevant in the context of anticipation. In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990) (When the claimed compositions are not novel they are not rendered patentable by recitation of properties, whether or not the properties are shown or suggested in the prior art).

The examiner does not, however, rely on extrinsic evidence in concluding that Nahm's antibody inherently binds mammalian cells. In this regard, appellants argue that the terminal N-acetylglucosamine on the group A Streptococcal carbohydrate is attached through carbon atom 1 to carbon atom 3 of rhamnose by a $1 linkage, while a terminal N-acetylglucosamine on a mammalian cell is attached through carbon atom 1 to carbon atom 2 of mannose by a $1 linkage. The implication is that an antibody specific for a determinant involving the attachment of N-acetylglucosamine to rhamnose will not necessarily bind N-acetylglucosamine attached to mannose. Brief, pages 23 and 24. In our view, this is not a completely satisfactory argument as it does not come to grips with the fact that HGAC-1 binds N-acetylglucosamine conjugated to BSA, and thus recognizes the N-acetylglucosamine hapten itself, rather than its point of attachment to the Group A carbohydrate.

Additionally, appellants rely on the declaration of Dr. Rook (paper no. 22, April 14, 1993; resubmitted as Exhibit D with the Brief), wherein Dr. Rook contends that "[m]ost monoclonal antibodies . . . raised against the bacterial cell walls of Group A Streptococcus do not have the properties of the monoclonal antibodies of the present invention (the ability to bind to mammalian cells or membranes . . . containing terminal N-acetylglucosamine residues)." This is a statement of fact, which we accept at face value. Nevertheless, it is conspicuous for what it does not say. N-acetylglucosamine is a major antigenic determinant on group A strep, but it is not the only one. Clearly, some antibodies raised

against group A streptococci cell walls would recognize other determinants, and would not bind N-acetylglucosamine, no matter how presented. The relevant question is whether most (or any) monoclonal antibodies recognizing both the terminal N-acetylglucosamine on group A streptococcus and N-acetylglucosamine conjugated to BSA (as is the case with Nahm's antibody) would "not have the properties of the monoclonal antibodies of the present invention (the ability to bind mammalian cells or membranes . . . containing terminal N-acetylglucosamine)." The declaration does not address this point.

In our opinion, neither of appellants' arguments is particularly compelling. On the other hand, it cannot be said that the extrinsic evidence relied on by the examiner establishes that HGAC-1 necessarily possesses all the binding properties required by the claims.[6] Inasmuch as "[t]he Patent Office has the initial duty of supplying the factual basis for its rejection," and "we may not resolve doubts in favor of the Patent Office determination

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[6] We note that the examiner, although relying on a theory of inherency, did not invoke the principles of In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433-434 (CCPA 1977):

> Where, as here, the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product . . . . Whether the rejection is based on 'inherency' under 35 U.S.C. § 102, on 'prima facie obviousness' under 35 U.S.C. § 103, jointly or alternatively, the burden of proof is the same, and its fairness is evidenced by the PTO's inability to manufacture products or to obtain and compare prior art products [footnote omitted].

Nevertheless, we take no position on whether the facts of this case, as developed on this record, justify shifting the burden of proof to appellants.

when there are deficiencies in the record as to the necessary factual bases supporting" its determination, In re Warner, 379 F.2d 1011, 1017, 154 USPQ 173, 178 (CCPA 1967), cert. denied, 389 U.S. 1057 (1968), we find that the examiner has not established that Nahm anticipates the claimed invention.

Turning to the aspect of the examiner's rejection relating to the obviousness of the claimed invention, we find little more than a restatement of the anticipation aspect of the rejection ("[T]he information in [Nahm] specifically characterizing the anti-strep A antibodies . . . provided to a skilled worker in the art would have produced a monoclonal antibody having the same specificities and function as instantly claimed, with a reasonable expectation of success" Examiner's Answer, pages 5 and 6). We have already determined that, on this record, Nahm's antibody cannot be said to inherently possess all of the properties required by the present claims. Nor, as appellants point out, does the examiner identify anything in the prior art which would suggest raising antibodies against Group A Streptococci and isolating those capable of binding both the terminal N-acetylglucosamine on the Group A Strep carbohydrate and mammalian cells. Thus, we find this aspect of the rejection to be without merit.

Accordingly, on this record, we are constrained to reverse the rejection of claims 22, 24, 32, 34, 35, 37, 45, 47, 48, 50, 60, 61, 63 and 73 under 35 U.S.C. § 102(b) as anticipated by Nahm and Katz, or in the alternative, under 35 U.S.C. § 103 as unpatentable over Nahm and Katz.

REVERSED

William F. Smith Administrative Patent Judge	)
Toni R. Scheiner Administrative Patent Judge	) BOARD OF PATENT)) APPEALS AND)) INTERFERENCES
Eric Grimes Administrative Patent Judge	)

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